

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: AOKI et al) Examiner: Anish Gupta
Serial Number: 09/490,756) Art Unit: 1653
Filed: January 24, 2000)
For: METHOD FOR TREATING DYSTONIA)
WITH BOTULINUM TOXIN TYPE B) Irvine, California

DECLARATION UNDER 37 C.F.R. SECTION 1.132

I, MITCHELL F. BRIN, declare as follows:

1. I am over the age of twenty one, competent to testify in a court of law, and could and would testify to the matters set forth below before the United States Patent and Trademark Office, if required to do so.

2. I understand that this declaration will be used to assist prosecution of United States patent application serial number 09/490,756, including to assist to overcome a rejection in the November 8, 2000 office action in serial number 09/490,756.

3. I graduated from the University of Pennsylvania in 1975 with a bachelor of arts in biology (Magna Cum Laude and Phi Beta Kappa) and I received an M.D. degree from the Columbia College of Physicians and Surgeons. I completed neurology and fellowship training at the Columbia University Neurological Institute. In 1994, I joined the Mount Sinai Medical Center as an Associate Professor and Director of the Movement Disorders Program.

I was most recently, attending Physician and Associate Professor of Neurology at the Mount Sinai School of Medicine in New York where I also served as Director of Movement Disorders and held the Bachmann-Strauss Endowed Chair in Neurology. I have directed numerous neurological research programs relating to use of a botulinum toxin in the treatment of movement disorders, such as dystonia.

I was one of the first investigators to examine the use of botulinum toxin for the treatment of medical disorders and I pioneered the use of botulinum toxin for the

treatment of dystonias, including blepharospasm and other debilitating neurological disorders. I have designed and conducted double blind studies examining the use of botulinum toxin for numerous conditions, and have conducted a number of multicenter studies for uses of botulinum toxin.

I founded the American Academy of Neurology course on botulinum toxin, and I have organized numerous courses and symposia on botulinum toxin, and has published extensively on this subject.

I hold many appointments and affiliations, including President and Founder of WE MOVE, an international professional and patient educational not-for-profit organization that focuses on movement disorders. I also serve on the board of directors of the Bachmann-Strauss Dystonia and Parkinson Foundations and the Exceptional Parent Foundation. I serve on the review board of the United States Pharmacopeial Convention and the Steering Committee of the World Congress on Disabilities. I am a member of the American Academy of Neurology Section on Movement Disorders and Co-Founder of the Dystonia Study Group.

I also serve on the editorial and peer-review boards of numerous scientific journals and on the steering committee of the World Congress on Disabilities. I am the recipient of many awards including being elected a Fellow to the American Academy of Neurology; recipient of the FDA's Commissioner's Special Citation for my work with neurological movement disorders; and a Distinguished Service and Honor Award from the American Otolaryngology Society.

A partial list of my publications is attached to this declaration as Appendix A.

By training and experience I am an expert in the therapeutic use of the botulinum toxins, including use of botulinum toxin type B to treat dystonia.

4. I am currently employed by Allergan, Inc, the assignee of the above-identified patent application, as Vice President, *Botox*[®]/Neurology. In this capacity, I oversee the *Botox*[®] (botulinum toxin type A purified neurotoxin complex) development portfolio, and direct clinical programs for uses of the botulinum toxins.

5. I am the co-author of Jankovic J, and Brin M., *Therapeutic Uses of Botulinum Toxin*, New Eng J. Med, 1186-1194;1991 (the "Jankovic reference").

6. The Jankovic reference discusses therapeutic uses of *only* type A botulinum toxin. As of the April 25, 1991 date of the Jankovic reference it was completely unknown as to whether or not botulinum toxin type B would have any therapeutic efficacy in human. Indeed, as far as I am aware, the first reported use of type B botulinum toxin in humans did not occur until 1995.

7. Additionally, the Jankovic reference does not state that botulinum type B can be used as an alternative or in place of botulinum type A, although it does speculate on page 1189, that other botulinum toxins, immunologically distinct from the type A toxin, may have some utility to treat patients who have become non-responsive to type A toxin due to a development of antibodies to the type A toxin.

8. In my opinion, prior to December 28, 1993, it would have been foolhardy and dangerous to use botulinum toxin type B to treat patients with dystonia, such as cervical dystonia, in light of the complete lack of clinical experience with the type B toxin as of that date. Certainly, the 1991 Jankovic reference does not teach, suggest, motivate or recommend use of botulinum toxin type B by physicians to treat any dystonic patients.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that any such willful false statements may jeopardize the validity of the above-identified application or any patent issuing therefrom.

Executed this 8 day of February, 2001, at Irvine, California.



Mitchell F. Brin

ATTACHMENT A

PUBLICATIONS OF MITCHELL F BRIN

A. Original, Peer Reviewed Publications

1. ⁱWormser GP, Donath J, Kennish A, Brin MF, Sanders M. Fatal pneumonia. NYS J Med 1981;1088-1089.
2. [†]Brin MF, Fetell MR, Green PHA, Kayden HJ, Hays AP, Behrens MM, Baker H. Blind loop syndrome, vitamin E malabsorption, and spinocerebellar degeneration. Neurology 1985;35:338-342.
3. Bressman S, Fahn S, Eisenberg M, Brin M, Maltese W. Biotin-responsive encephalopathy with myoclonus, ataxia, and seizures. Adv Neurology 1985;43:119-125
4. Lange DJ, Warner C, Brin M, List T, Fahn S, Lovelace RE. Botulinum toxin therapy: distant effects on neuromuscular transmission. Muscle Nerve 1985;8:624-625.
5. Blitzer A, Lovelace RE, Brin MF, Fahn S, Fink ME. Electromyographic findings in focal laryngeal dystonia (spastic dysphonia). Ann Oto, Rhino, and Laryngoscope 1985; 94:591-594.
6. [†] Brin MF, Pedley TA, Lovelace RE, Emerson RG, Gouras P, MacKay C, Kayden HJ, Levy J, Baker H. Electrophysiological features of abetalipoproteinemia: functional consequences of vitamin E deficiency. Neurology 1986; 36:669-673.
7. Breakefield XO, Bressman SB, Kramer PL, Ozelius LO, Moskowitz C, Tanzi R, Brin MF, Hobbs W, Kaufman D, Kidd KK, Fahn S, Gusella J. Linkage analysis in a family with dominantly inherited torsion dystonia: Exclusion of the pro-opiomelanocortin and glutamic acid decarboxylase genes, and other chromosomal regions using DNA polymorphisms. J Neurogenetics 1986;3:159-175.
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9. Blitzer A, Brin MF, Fahn S, Lange D, Lovelace RE. Botulinum toxin for the treatment of spastic dysphonia. Laryngoscope 1986;96:1300-1301.
10. Lange DJ, Brin M, Warner C, Fahn S, Lovelace RE. Distant effects of local

injections of botulinum toxin. *Muscle Nerve* 1987;10:552-555.

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12. de Yebenes JG, Brin MF, Mena MA, De Felipe C, del Rio MR, Bazan E, Martinez A, Fahn S, del Rio J, Vazquez A. Neurochemical findings in neuroacanthocytosis. *Movement Disorders* 1988;3:300-312.
13. Blitzer AB, Brin MF, Fahn S, Lovelace RE. Localized injections of botulinum toxin for the treatment of focal laryngeal dystonia (spastic dysphonia). *Laryngoscope* 1988;98:193-197.
14. Blitzer AB, Brin MF, Fahn S, Lovelace RE. Clinical and laboratory characteristics of laryngeal dystonia: A study of 110 cases. *Laryngoscope* 1988;98:636-640.
15. Vatassery GT, Brin MF, Fahn S, Kayden HJ, Traber MG. Effect of high doses of dietary vitamin E on concentrations of vitamin E in several brain regions, plasma, liver and adipose tissue. *J Neurochem* 1988;51:621-623.
16. Kaplan JG, Pack MD, Horoupian D, DeSouza T, Brin MF, Schaumburg H. Distal axonopathy associated with chronic gluten enteropathy: A treatable disorder. *Neurology* 1988;38:642-645.
17. Younger DS, Chou S, Hays AP, Lange DJ, Emerson R, Brin MF, Thompson H, Rowland, LP. Primary lateral sclerosis: A clinical diagnosis re-emerges. *Arch Neurol* 1988;45:1304-7.
18. Blitzer A, Brin MF, Fahn S. Botulinum toxin injection for the treatment of oromandibular dystonia. *Ann Oto Rhino Laryngol* 1989;98:93-97.
19. † Brin MF, Blitzer A, Fahn S, Gould W, Lovelace RE. Adductor laryngeal dystonia (spastic dysphonia): Treatment with local injections of botulinum toxin (BOTOX). *Movement Disorders* 1989;4:287-296.
20. Ozelius L, Kramer PL, Moskowitz CB, Kwaitkowski J, Brin MF, Bressman SB, Schuback DE, Falk CT, Risch N, de Leon D, Burke RE, Haines J, Gusella JF, Fahn S, Breakefield XO. Human gene for torsion dystonia located on chromosome 9q32-q34. *Neuron* 1989;2:1427-1434.
21. Bressman SB, de Leon D, Brin MF, Risch N, Burke RE, Greene PE, Shale H, Fahn S. Idiopathic dystonia among Ashkenazi Jews: Evidence for autosomal dominant inheritance. *Ann Neurol* 1989;26:612-620.
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23. Parkinson Study Group. DATATOP: A multi-center controlled clinical trial in early Parkinson's disease, *Archives of Neurology* 1989; 46:1052-1060.
24. Parkinson Study Group. Effect of deprenyl on the progression of disability in early Parkinson's disease. *New England Journal of Medicine* 1989; 321:1364-1371.
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29. American Academy of Otolaryngology-Head and Neck Surgery. Academy policy statement: Botox for spasmodic dysphonia. *AAO-HNS Bulletin* 1990;9:8.
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33. Lange DJ, Rubin M, Greene PE, Kang UJ, Moskowitz CB, Brin MF, Lovelace RE, Fahn S. Distant effects of locally injected botulinum toxin: A double-blind study of single fiber EMG changes. *Muscle Nerve* 1991;14:672-675.

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50. Bressman SB, Hunt AL, Heiman GA, Brin MF, Burke RE, Fahn S, Trugman JM, de Leon D, Kramer PL, Wilhelmsen KC, Nygaard T. Exclusion of the DYT1 locus in a non-Jewish family with early-onset dystonia. *Mov Disord* 1994;9:626-32
51. *Grillone GA, Blitzler A, Brin MF, Annino DJ, Saint Hilaire MH. Treatment of adductor laryngeal breathing dystonia with botulinum toxin. *Laryngoscope* 1994;104:30-32.
52. *,† Keen M, Blitzler A, Aviv J, Binder W, Prystowsky J, Smith H, Brin MF. Botulinum Toxin for hyperkinetic facial lines: results of a double blind placebo controlled study. *Plast Reconstr Surg* 1994;94:94-99.
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57. *,† Braun N, Abd A, Baer J, Blitzler A, Stewart C, Brin M. Dyspnea in dystonia. A functional evaluation. Chest 1995;107:1309-16.
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*: Publication subsequent to promotion to Associate Professor
 †: Brin is primary or senior author

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APR 18 1994

PATENT DEPT.

Page 1 of 2

ASSIGNMENT

Docket No. 1949

WHEREAS, WE, K. Roger Aoki, Michael W. Grayston, Steven R. Carlson, and Judith M. Leon, all citizens of the United States of America, residing at 25472 Earhart Road, Laguna Hills, CA 92653; 12 Mandarin, Irvine, CA 92714; 29991 Happy Sparrow Lane, Laguna Niguel, CA 92677, and 29992 Running Deer Lane, Laguna Niguel, CA 92677, respectively, have invented certain new and useful improvements in USE OF BOTULINUM TOXINS FOR TREATING VARIOUS DISORDERS AND CONDITIONS AND ASSOCIATED PAIN for which application for Letters Patent of the United States was filed on December 28, 1993 under application number 08/173,996.

WHEREAS, ALLERGAN, INC., a Delaware Corporation, 2525 Dupont Drive, Irvine, California 92715 is desirous of obtaining the entire right, title and interest in the said improvements and the said application: USE OF BOTULINUM TOXINS FOR TREATING VARIOUS DISORDERS AND CONDITIONS AND ASSOCIATED PAIN

NOW, THEREFORE, in consideration of the sum of One Dollar (\$1.00) to each of us in hand paid, and other good and valuable consideration, the receipt of which is hereby acknowledged, we, the said inventors, do hereby acknowledge that we have sold, assigned, transferred and set over, and by these presents do hereby severally and jointly, sell, assign, transfer and set over, unto the said ALLERGAN, INC.

its successors, legal representatives and assigns, our respective rights, titles and interests, and the entire right, title, and interest throughout the world in, to and under the said improvements, and the said application and all divisions, renewals and continuations thereof, and all Letters Patent of the United States which may be granted thereon and all reissues and extensions thereof, and all rights of priority under International Conventions and applications for Letters Patent which may hereafter be filed for said improvements in any country or countries foreign to the United States, and all Letters Patent which may be granted for said improvements in any country or countries foreign to the United States and all extensions, renewals and reissues thereof; and we hereby authorize and request the Commissioner of Patents of the United States, and any Official of any country or countries foreign to the United States, whose duty it is to issue patents on applications as aforesaid, to issue all Letters Patent for said improvements to the said ALLERGAN, INC.

its successors, legal representatives and assigns, in accordance with the terms of this instrument.

AND WE HEREBY covenant and agree that we will communicate to the said ALLERGAN, INC.

its successors, legal representatives and assigns, any facts known to us respecting said improvements, and testify in any legal proceeding, sign all lawful papers, execute all divisional continuing and reissue applications, make all rightful oaths and generally do everything possible to aid the said ALLERGAN, INC.

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ASSIGNMENT - Page . of 2

APR 18 1994

cket No. 1949

PATENT DEPT.

its successors, legal representatives and assigns, to obtain and enforce proper patent protection for said improvements in all countries.

IN TESTIMONY WHEREOF, I hereunto set my hand and seal this 4th day of January, 1994.

State of CALIFORNIA

K. Roger Aoki
ss.: K. Roger Aoki

County of ORANGE

On this 4th day of JANUARY, 1994, before me a Notary Public in and for the State and County aforesaid, personally appeared K. ROGER AOKI known to me to be the person of that name, who signed and sealed the foregoing instrument, and acknowledged the same to be his free act and deed.

SEAL



Mary Lou McNown

IN TESTIMONY WHEREOF, I hereunto set my hand and seal this 6th day of JANUARY, 1994.

State of CALIFORNIA

Michael W. Grayston
ss.: Michael W. Grayston

County of ORANGE

On this 6th day of JANUARY, 1994, before me a Notary Public in and for the State and County aforesaid, personally appeared MICHAEL W. GRAYSTON known to me to be the person of that name, who signed and sealed the foregoing instrument, and acknowledged the same to be his free act and deed.

SEAL



Mary Lou McNown

REEL

IN TESTIMONY WHEREOF, I hereunto set my hand and seal this 18th day of January, 1994.

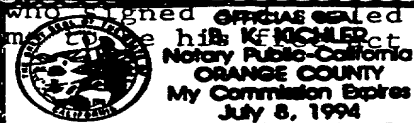
State of CALIFORNIA

Steven R. Carlson
ss.: Steven R. Carlson

County of ORANGE

On this 18th day of January, 1994, before me a Notary Public in and for the State and County aforesaid, personally appeared Steven R. Carlson known to me to be the person of that name, who signed and sealed the foregoing instrument, and acknowledged the same to be his free act and deed.

SEAL



Steven R. Carlson

IN TESTIMONY WHEREOF, I hereunto set my hand and seal this 20th day of January, 1994.

State of CALIFORNIA

Judith M. Leon
ss.: Judith M. Leon

County of ORANGE

On this 20th day of January, 1994, before me a Notary Public in and for the State and County aforesaid, personally appeared JUDITH M. LEON known to me to be the person of that name, who signed and sealed the foregoing instrument, and acknowledged the same to be his free act and deed.

SEAL



Mary Lou McNown

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	AOKI, <i>et al.</i>) Examiner: (Parent App.: A. Gupta)
)
Serial No.:	Pending) Art Unit: (Parent App.: 1654)
)
Filed:	Submitted herewith)
)
For:	METHOD FOR TREATING)
	DYSTONIA WITH BOTULINUM)
	TOXIN TYPE B) Irvine, California

ASSOCIATE POWER OF ATTORNEY

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Please recognize Stephen Donovan, Reg. No. 33,433, as an Associate Attorney in the above-identified patent application, with full power to prosecute said application, to make alterations and amendments therein, to receive and respond to all communications from the United States Patent & Trademark Office, and to transact all business in the United States Patent & Trademark Office related thereto.

Please direct all correspondence and inquiries to:

Stephen Donovan
Senior Patent Attorney
Allergan, Inc.
2525 Dupont Drive
Irvine, CA 92612
Telephone: 714 246 4026
Fax: 714 246 4249

Respectfully submitted,

Date: January 18, 2000

By: Martin A. Voet
Martin A. Voet, Reg. No. 25,208
Allergan, Inc.
2525 Dupont Drive
Irvine, CA 92612
Telephone: 714 246 5894

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8

I hereby certify that this Associate Power of Attorney and any additional documents set forth as being enclosed herein are being deposited with the United States Postal Service on the date shown below, with sufficient postage as first class mail in an envelope addressed to Assistant Commissioner for Patents, Washington, DC 20231.

Mary Stickle
Name of person mailing paper

Mary Stickle
Signature of person mailing paper

Date: January 18, 2000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: AOKI, *et al.*) Examiner: (Parent App.: A. Gupta)
U.S. Serial No.: PENDING) Art Unit: (Parent App.: 1654)
Filed: HERewith)
For: METHOD FOR TREATING)
DYSTONIA WITH BOTULINUM)
TOXIN TYPE B) Irvine, California

INFORMATION DISCLOSURE STATEMENT

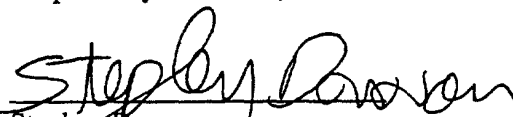
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Applicant wishes to call to the attention of the Examiner the documents cited on the accompanying one-page Form PTO-1449. No concession is made that these documents are prior art, and applicant expressly reserves the right to antedate the documents as may be appropriate. Applicant requests that each of these documents be made of record in the above-identified application.

Many of these documents were cited in one or both of related applications Serial No. 08/627,118 filed April 3, 1996 and Serial No. 08/173,996 filed December 28, 1993. Therefore, only copies of those documents not cited in either of the prior related applications are enclosed.

Respectfully submitted,


Stephen Donovan
Registration Number 33,433


Date: January 14, 2000

Allergan, Inc.
2525 Dupont Drive
Irvine, CA 92612
Telephone: 714 246 4026
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CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8

I hereby certify that this Information Disclosure Statement and any additional documents set forth as being enclosed herein are being deposited with the United States Postal Service on January 18, 2000, with sufficient postage as first class mail in an envelope addressed to Assistant Commissioner for Patents, Washington, DC 20231.

MARY STICKLE
Name of person mailing paper


Signature of person mailing paper

Date: January 18, 2000

LIST OF ART CITED BY APPLICANT

ATTY. DOCKET: 16952CON1DIV8	SERIAL NO.: PENDING
APPLICANT: AOKI ET AL	TITLE: METHOD FOR TREATING DYSTONIA WITH BOTULINUM TOXIN TYPE B
FILING DATE: SUBMITTED HEREWITH	GROUP:

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE (if applicable)
	AA	2373454	4/45	BUMY ET AL			
	AB	3132995	5/64	BERGER ET AL			
	AC	4713240	12/87	WILKINS ET AL			
	AD	4832936	6/90	DYSTRA ET AL			
	AE	5056291	10/91	LAM ET AL			
	AF	5055302	10/91	LATIES ET AL			
	AG	5053005	10/91	BORODIC			
	AH	5183462	2/93	BORODIC			
	AI	2719102	9/55	BALDWIN			
	AJ	5766605	6/98	SANDERS ET AL			
	AK	5437291	8/95	PASRICHA ET AL			

FOREIGN PATENT DOCUMENTS

		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION (yes/no)
	AL	95/28171	PCT				

OTHER ART

(Including Author, Title, Date, Pertinent Pages, etc.)

	AM	CORRESPONDENCE DATED 12/10/91 BETWEEN WILLIAM C. SHEPHERD AND IRA SANDERS
	AN	CORRESPONDENCE DATED 4/13/92 BETWEEN IRA SANDERS AND ANGELIKA S. ASWAD REGARDING "ANIMAL STUDY"
	AO	PARTIAL CORRESPONDENCE DATED 4/24/92 BETWEEN ANGELIKA S. ASWAD AND DR. SANDERS REGARDING "BOTULINUM TOXIN TO DECREASE SALIVARY FLOW"
	AP	AMBACHE, J. PHYSIOL. (1951) 113, 1-17.
	AQ	AMBACHE, J. PHYSIOL. (1949) 108, 127-141.
	AR	BRIN; ARCH. DE NEUROBIOL. 54. SUPL. 3 (7-23) 1991.
	AS	JENZER ET AL; SCHWEIZ. MED. WSCHR. (1974); 104, 685-693 (w/ English translation).
	AT	POUNGVARIN ET AL; J. MED. ASSOC. THAI. (1992 Apr) 75 (4) 199-203.

EXAMINER _____

DATE CONSIDERED _____

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	AOKI et al.)	Examiner: Anish Gupta
)	
U.S. Serial No.:	09/490,756)	Art Unit: 1653
)	
Filed:	January 24, 2000)	
)	
For:	METHOD FOR TREATING DYSTONIA)	
	WITH BOTULINUM TOXIN TYPE B)	Irvine, California

**SUPPLEMENTARY
INFORMATION DISCLOSURE STATEMENT**

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Applicant provides with regard to the above-referenced patent application one copy of each of the thirteen documents listed on the attached two-page Form PTO-1449, which may be material to the examination of this application, and in respect of which there may be a duty of disclosure under 37 C.F.R. §1.56.


While these documents may be material pursuant to 37 C.F.R. §1.56, their disclosure is not intended to constitute an admission that any such document is prior art in regard to this invention. The filing of this Statement should not be construed to mean that a search has been conducted or that no other material documents or information exists. Please do not hesitate to contact the undersigned should any questions arise regarding this Statement.

The Commissioner is hereby authorized to charge any fees associated with this communication, or credit any overpayment, to Deposit Account No. 01-0885.

Respectfully submitted,

Allergan, Inc.
2525 Dupont Drive
Irvine, CA 92612

Date: July 10, 2000


Stephen Donovan
Registration Number 33,433
Tel: 714 246 4026
Fax: 714 246 4249

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8

I hereby certify that this Supplementary Information Disclosure Statement and any additional documents set forth as being enclosed herein are being deposited with the United States Postal Service on the date shown below, with sufficient postage as first class mail in an envelope addressed to Assistant Commissioner for Patents, Washington, DC 20231.

Date: July 11, 2000

Mary Stickle
Name of Person Mailing
Mary Stickle
Signature of Person Mailing

**SUPPLEMENTAL
LIST OF ART CITED BY APPLICANT**

ATTY. DOCKET: 16952CON1DIV8	SERIAL NO.: 09/490,756
APPLICANT: AOKI ET AL	TITLE: METHOD FOR TREATING DYSTONIA WITH BOTULINUM TOXIN TYPE B
FILING DATE: 01/24/00	GROUP: 1653

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE (if applicable)
	AA	5,298,019	3/1994	Borodic			
	AB	5,401,243	3/1995	Borodic			
	AC	5,696,077	12/1997	Johnson et al.			
	AD						
	AE						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION (yes/no)
	BA	94/00481	1/1994	PCT			
	BB						
	BC						

OTHER ART

(Including Author, Title, Date, Pertinent Pages, etc.)

CA	Greene, Paul E., et al.; <i>Response to Botulinum Toxin F in Seronegative Botulinum Toxin A-Resistant Patients; Movement Disorders</i> ; Vol. 11, No. 2; pp. 181-184 (March 1996).
CB	Moyer, E.D., et al.; <i>Effects of Intramuscular Injection of Botulinum Toxin Type B in Nonhuman Primates; Botulinum and Tetanus Neurotoxins—Neurotransmission and Biomedical Aspects</i> ; Bibhuti R. Dasgupta, Editor; Plenum Press (1993).
CC	Price, J., et al.; <i>A Comparative Study of Tear Secretion in Blepharospasm and Hemifacial Spasm Patients Treated with Botulinum Toxin; Journal of Clinical Neuro-Ophthalmology</i> ; Vol. 13, No. 1; pp. 67-71 (March 1993). Abstract only.
CD	Scott, Alan B., et al.; <i>Systemic Toxicity of Botulinum Toxin by Intramuscular Injection in the Monkey; Movement Disorders</i> ; Vol. 3, No. 4; pp. 333-335 (1988).
CE	Truong, Daniel D., et al.; <i>BotB (Botulinum Toxin Type B): Evaluation of Safety and Tolerability in Botulinum Toxin Type A-Resistant Cervical Dystonia Patients (Preliminary Study); Movement Disorders</i> ; Vol. 12, No. 5; pp. 772-775 (Sep 1997).

EXAMINER _____

DATE CONSIDERED _____

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

**SUPPLEMENTAL
LIST OF ART CITED BY APPLICANT**

ATTY. DOCKET: 16952CON1DIV8	SERIAL NO.: 09/490,756
APPLICANT: AOKI ET AL	TITLE: METHOD FOR TREATING DYSTONIA WITH BOTULINUM TOXIN TYPE B
FILING DATE: 01/24/00	GROUP: 1653

OTHER ART (Continued)
(Including Author, Title, Date, Pertinent Pages, etc.)

	CF	Tsui, J.K., et al.; <i>A Pilot Study on the Use of Botulinum Toxin in Spasmodic Torticollis</i> ; <u>The Canadian Journal of Neurological Sciences</u> ; Vol. 12, No. 4; pp. 314-316 (Nov 1985).
	CG	Tsui, Joseph K.C., et al.; <i>Local Treatment of Spasmodic Torticollis with Botulinum Toxin</i> ; <u>Le Journal Canadien des Sciences Neurologiques</u> ; Vol. 14, No. 3 (Supplement); pp. 533-535 (August 1987).
	CH	Med Ad News staff; <i>Athena Makes a Wise Move</i> ; <u>Medical Advertising News</u> ; page 4 (November 1992).
	CI	U.S. Food and Drug Administration; <i>List of Orphan Designations and Approvals</i> ; pp. 1 and 42-46 of 275 (computer search printout dated Jan. 18, 2000).
	CJ	
	CK	
	CL	
	CM	
	CN	
	CO	
	CP	
	CQ	

EXAMINER _____

DATE CONSIDERED _____

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

As a below-named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

~~USE OF BOTULINUM TOXINS FOR TREATING VARIOUS DISORDERS AND CONDITIONS AND ASSOCIATED PAIN~~
the specification of which

(check one)

EX is attached hereto.

☒ was filed on December 28, 1993 as Application Serial No. 08/173,996 and was amended on

(if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by an amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119, of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)

Priority Claims

(Number)	(Country)	(Day/Month/Year Filed)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
(Number)	(Country)	(Day/Month/Year Filed)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
(Number)	(Country)	(Day/Month/Year Filed)	<input type="checkbox"/> Yes	<input type="checkbox"/> No

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)
(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

POWER OF ATTORNEY

As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith:

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Full Name of Sixth Joint Inventor (if any):	
Sixth Inventor's Signature:	Date Signed:
Residence (City, State and/or Country):	Citizenship:
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Full Name of Seventh Joint Inventor (if any):	
Seventh Inventor's Signature:	Date Signed:
Residence (City, State and/or Country):	Citizenship:
Post Office Address (Street, City, State, Zip Code, Country):	